MAR 8 2006

K052989

DP240

240 HOUR DOPPLER PROBE

Appendix 2A

510(k) SUMMARY

(1) Submitter's information

Name:	Deltex Medical Limited
Address:	Terminus Road
	Chichester
	West Sussex
	PO19 8TX
	U.K.
	Official Correspondent: Lawrence Brookfield - Quality Assurance & Regulatory Affairs Manager
Telephone:	011 44 1243 523174
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Date prepared: 18 October, 2005

(2) Device Identification

Proprietary name:	240 Hour Doppler Probe
Common/usual name:	DP240
Classification name:	Extravascular blood flow probe

(3) Identification of predicate devices

The DP240 is substantially equivalent to the following previously cleared devices:

Deltex Medical *CardioQ Probe* as described in 510(k) No. K031706.

Arrow International *Hemosonic 100 Esophageal Probe* as described in 510(k) No. K972798

(4) Device Description and Intended Use

When used in conjunction with the *CardioQ* cardiac output and fluid status monitoring system (K031706), the DP240 is designed to provide clinicians with real-time information about left-ventricular function by measuring blood flow in the descending thoracic aorta. The probe is designed to operate in a clinical setting in which patients are under general anesthesia or sedated in the intensive care unit.

The DP240 transmits a 4 MHz continuous wave ultrasonic 'carrier' signal from the probe tip at a fixed angle to the descending aorta, by excitation of a piezo-electric transducer. The ultrasound is reflected by the red blood cells and is received by a separate transducer in the probe tip.

The DP240 is placed orally or nasally and inserted into the esophagus to a depth of 35 – 45 cm, (approx. 14" – 18") for insonation of the descending thoracic aorta at the 6th thoracic vertebra (approximately). The shaft and tip of the DP240 is the only component in contact with the patient and is manufactured with an outer insulating cover of medical grade silicone rubber. The probe is flexible and has a shaft diameter of 14 French (~4.8 mm. approx. 0.18"). The probe is supplied sterile and is for single-use only in adults.

K052989

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2006

Mr. Lawrence Brookfield
Quality Assurance & Regulatory Affairs Manager
Deltex Medical Limited
Terminus Road
Chichester PO19 8TX
U. K.

Re: K052989
Trade Name: DP240 240 Hour Doppler Probe
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood Flow Probe
Regulatory Class: Class II (two)
Product Code: DPT
Dated: January 30, 2006
Received: February 2, 2006

Dear Mr. Brookfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K052989

510(k) Number (if known): ~~Unknown - not yet assigned by FDA~~.

Device Name:

DP240, *240 Hour Doppler Probe*

Indications For Use:

When used in conjunction with the *CardioQ* cardiac output and fluid status monitoring system, the DP240 is designed to provide clinicians with real-time information about left-ventricular blood flow. The DP240 is designed to operate in a clinical setting in which the patients are under general anesthesia or are sedated in the intensive care unit. The DP240 can be placed into the esophagus via oral or nasal insertion in adults.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Symmons

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052989